Exhibit 4

Assisted suicide by oxygen deprivation with helium at a Swiss right-to-die organisation

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Received 7 August 2009
Revised 1 November 2009
Accepted 5 November 2009

ABSTRACT

Background In Switzerland, right-to-die organisations assist their members with suicide by lethal drugs, usually barbiturates. One organisation, Dignitas, has experimented with oxygen deprivation as an alternative to sodium pentobarbital.

Objective To analyse the process of assisted suicide by oxygen deprivation with helium and a common face mask and reservoir bag.

Method This study examined four cases of assisted suicide by oxygen deprivation using helium delivered via a face mask. Videos of the deaths were provided by the Zurich police. Dignitas provided protocol and consent information.

Results One man and three women were assisted to death by oxygen deprivation. There was wide variation in the time to unconsciousness and the time to death, probably due to the poor mask fit. Swiss law prevented attendants from effectively managing the face mask apparatus. Purposeless movements of the extremities were disconcerting for Dignitas attendants, who are accustomed to assisting suicide with barbiturates. None of the dying individuals attempted self-rescue.

Conclusions The dying process of oxygen deprivation with helium is potentially quick and appears painless. It also bypasses the prescribing role of physicians, effectively demedicalising assisted suicide. Oxygen deprivation with a face mask is not acceptable because leaks are difficult to control and it may not eliminate rebreathing. These factors will extend time to unconsciousness and time to death. A hood method could reduce the problem of mask fit. With a hood, a flow rate of helium sufficient to provide continuous washout of expired gases would remedy problems observed with the mask.

In Switzerland, Article 115 of the Penal Code makes assisted suicide punishable only if it is performed with selfish motives.[1–3] While this legal situation makes it possible for anyone to assist in suicide, as long as there is no selfish motive, right-to-die organisations have led the development of an open practice that ensures routine reporting of assisted suicides to the authorities for criminal investigation.[2 3] Every year there are several hundred such deaths and prosecutions are very rare.[1]

The two largest Swiss right-to-die organisations were established in 1982. In Zurich, Exit Deutsche Schweiz was founded for German-speaking members. In Geneva, Exit ADMD (Association pour le droit de mourir) was founded for French-speaking members.[1] In 1998, Ludwig A Minelli, a human rights lawyer, founded Dignitas—To live with dignity—To die with dignity. Foreigners make up the majority of suicides assisted by Zurich-based Dignitas, thus the organisation is frequently characterised as a destination for 'suicide tourism' (table 1).[3] This suicide tourism was the subject of an acclaimed 2007 documentary, 'The suicide tourist', which aired on television networks in several countries. The documentary showed the assisted suicide of a terminally ill man who drank sodium pentobarbital.[4]

There is a fundamental difference between Switzerland and other jurisdictions that permit assisted suicide. In Belgium, The Netherlands, Oregon and Washington, patients must request assistance from a physician, who then evaluates the patient's eligibility with regard to terminal illness or unbearable suffering.[5–7] In Switzerland, it is right-to-die groups that evaluate requests for suicide assistance in accordance with the person's prognosis, suffering and disability.[1–3] Under the Swiss model, the role of physicians in suicide assistance is generally limited to assessing competence and prescribing a lethal dose of sodium pentobarbital. The drug is usually stored by the right-to-die organisation. Someone from the organisation, who is normally not a doctor or nurse, assists by preparing the drug and handing it to the patient/member to drink.[3]

In some cases, patients who have difficulty swallowing have self-administered the drug through a stomach tube or a percutaneous endoscopic gastrostomy catheter.[8] Swiss law allows an assistant to engage in preparatory activities such as setting up an intravenous drip, but it is legally critical that the individual member who wishes to die must carry out the final act independently.[1 8] Right-to-die organisations ensure that there is a witness to the final act, and in the case of Dignitas, it is routine to provide video evidence to the police, which helps to speed the criminal investigation.

On 31 January 2008 the medical director of the Canton of Zurich took the position that physicians must consult with patients more than once before prescribing sodium pentobarbital. Dignitas interpreted this as a signal that the cantonal medical director intended to restrict suicide assistance. It was also viewed as an obstacle to Dignitas' foreign members, particularly those who would delay their travel to Switzerland to a point at which return trips for further medical consultations were out of the question.[9]

Dignitas believed that the cantonal medical director's position infringed on a person's right to self-determination and the freedom of its resident physician to prescribe sodium pentobarbital. Therefore, Dignitas explored oxygen deprivation with helium as an alternative to an active pharmaceutical such as sodium pentobarbital. The application of a non-drug method would help Dignitas establish that medical control over assisted suicide is not necessary.[9]

Table 1 Number of assisted suicides by country and year (May 1998–31 December 2009)

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total	Total
Neighbouring countries														
Switzerland	6	4	3	11	17	9	14	12	15	6	10	4	111	11.66
Germany		1	4	31	50	45	66	78	120	75	59	35	564	59.24
Great Britain					1	15	10	15	26	17	23	27	134	14.08
France				2	4	12	3	12	16	18	19	7	93	9.77
Austria				1	2	2	2	3	2	3	4	3	22	2.31
Italy				1		2		4	2	1	1	4	15	1.58
Other countries														
Australia						1	1	1	1	4	1		9	0.95
Belgium						1					1		2	0.21
Czech Republic									1	1		1	3	0.32
Denmark									1			1	2	0.21
Greece				1									1	0.11
Hong Kong							1						1	0.11
Ireland						1	1	3				1	6	0.63
Israel				1		4	1			2	3	2	13	1.37
Canada							1		1	1	5	1	9	0.95
Hungary									1				1	0.11
Lebanon				1									1	0.11
Morocco								1			1		2	0.21
Mexico								1					1	0.11
Netherlands					1	1		1	2	2	1		8	0.84
New Zealand												1	1	0.11
Peru										1			1	0.11
Poland												1	1	0.11
Portugal												1	1	0.11
Spain				1		1	1	2	3	3	2		13	1.37
Sweden						2		2	3	2	2		11	1.16
Thailand									1				1	0.11
Uruguay							1						1	0.11
USA					1	4	3	3		2			13	1.37
													1041	100%

PHYSIOLOGY OF SUICIDE AND OXYGEN DEFICIENCY

Humans require sufficient oxygen to live. Without it, the body's oxygen cycle will break down and death will occur.[10] The effects of hypoxia (oxygen deficiency) are well known (table 2); sudden exposure to severe oxygen deficiency will result in loss of consciousness within 5–10 s and within 2 minutes permanent brain injury is probable.[11]

Dignitas intended to achieve oxygen deprivation by introducing near 100% of the inert gas helium into a mask, to replace the atmospheric air that participants are normally breathing. The composition of air is approximately 21% oxygen and 78% nitrogen, and thus the gas expired in the first few breaths may add sufficient oxygen to the inspired mixture to delay the effects of oxygen deficiency. To obtain the maximum advantage, the replacement of atmospheric air with helium must occur very rapidly. Humans can 'live' for several minutes while breathing very low concentrations of oxygen, so the system must almost immediately exclude expired breath, which normally contains approximately 14% oxygen.

This may be accomplished by one of two methods. One is to have a reservoir bag and mask apparatus similar to that used in clinical anaesthesia. To exclude expired breath totally, a system of two unidirectional valves directs expired gas to the atmosphere and allows helium to fill the reservoir bag, from which inspiration occurs. The other method is to introduce continuously into the reservoir a steady volume of 100% helium equal to or greater than two and a half times the individual's normal minute volume (approximately 10 litres per minute in an average adult).[12] This requires a flow metre in the system. Normal minute volumes for humans can be found in physiology texts. This continuous flow of helium acts to 'air condition' the reservoir bag by totally washing out expired gas. A critical necessity of these methods is a perfect fit of the mask to the face so that room air will not enter the system. This is an important matter—maintaining such a good fit often requires considerable expertise. Straps and harnesses are helpful, but they add a dangerous possibility of facilitating respiratory obstruction.

The use of inert gas, such as helium, for suicide and assisted suicide is a relatively recent trend.[13–20] Helium is non-flammable and non-toxic, and it is often chosen for suicide because its low odour and low viscosity make it very easy to breath.[21] This gas is also widely available, given its applications in industry and for party balloons.

Table 2 Progressive human response to oxygen-deficient atmosphere

Oxygen concentration (%)	Symptoms
12–16	Increase breathing/heart rate; slightly disturbed muscular coordination
10–14	Emotional upset; fatigue on exertion; breathing is disturbed; consciousness is not lost
6–10	Nausea; loss of free movement; possible collapse; may be aware but unable to move or speak; may lose consciousness
>6	Convulsive movement; gasping breaths; cessation of respiration and heart rate

Adapted from Clayton and Clayton.[11]

In brief, helium is used to replace oxygen. Human exposure to a 100% helium environment will result in the sudden loss of consciousness without warning.[11 20] Continued exposure will result in death from anoxia within a very few minutes.[11 20]

The suicide guidebook, 'Final exit', did not discuss inert gas methods when it was first published in 1991.[22] The 2002 edition, however, offers illustrated instructions on suicide with a plastic bag 'hood' filled with helium.[23]

METHODS

Materials

This study is based on videos of four assisted suicides by oxygen deprivation with helium, which occurred at Dignitas in the first quarter of 2008. Dignitas routinely provides video evidence of assisted suicides to the the Kantonspolizei Zurich (cantonal police), and the police return the videos after their investigation. In this instance, the copies returned by the police contained a technical malfunction that interfered with the playback. In April 2008, Dignitas' Ludwig Minelli arranged an appointment with the police so that the principal researcher could view the videos at the police station. At that time, the police corrected the technical error and provided copies of the videos to Minelli and the researcher. Dignitas also provided a German language copy of its client information sheet, the protocol for helium, and a blank copy of the client consent.

It is important to bear in mind that the videos are used to establish that the assisted suicides are lawful. As such, the videos are Dignitas property, shared for the purpose of researching the technical aspects of oxygen deprivation with helium. The Dignitas informed consent included the following clause, to which its members agreed:

> "I hereby declare that I am prepared to assist Dignitas in assembling its own data on the helium method, in my own interests as well as the interests of other members of Dignitas, and am therefore prepared to take these risks to myself into account." (translated from German)

Before data collection, the principal researcher submitted an ethics application to the Research Ethics Board (REB) at Kwantlen Polytechnic University, British Columbia, Canada. The REB responded with a series of questions about privacy, anonymity, terminal illness, Swiss right-to-die groups and secondary use of data. The researcher appeared before the REB to explain that the identities of persons receiving assisted suicide was not known and anonymity would be protected. In private, the REB deliberated and decided that secondary video analysis did 'not deal with human participants and so is not appropriate for review by the REB'. Therefore, the research was exempted from REB review.

The process of suicide by oxygen deprivation with helium

Dignitas members choosing to die from this method received training in two stages. First, they received a document entitled, 'Instructions and terms and conditions for informed consent'. This consent process explained why helium was being used instead of sodium pentobarbital, the known effects of helium, and a caution that Dignitas had little experience with this method for assisted suicide.

The second stage required that Dignitas members choosing to die by oxygen deprivation practise the correct placement of a mask that covered their nose, mouth and chin, in what was called the 'working position'. With the tubing disconnected from the helium tank, the mask would next be placed in a 'preparatory position' with the elastic band positioned over the ears and around the back of the head, and with the mask resting on the member's forehead. The member would practise moving the mask from the preparatory position to the working position (figure 1). Once the mask was in the working position, the member was instructed to place his or her hands at the sides of the body. The above process would be repeated until the Dignitas assistant was confident that the member could carry out the steps competently.

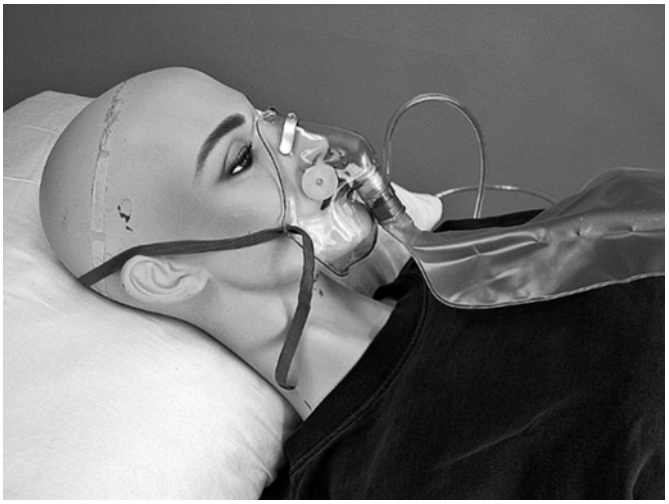

Figure 1 Mask in 'working position'. Mask is similar to type used by Dignitas for breathing helium (photo RD Ogden).

An additional instruction was that the member should exhale deeply immediately before placing the mask in the working position. According to Dignitas' protocol, this would have the effect of 'clearing the lungs of all used air so that the breathing with helium functions properly'. We believe that this forced expiration, although it may result in a deeper inhalation, would have little or no significant effect on the process of oxygen deprivation.

The protocol required that the member confirm that she or he was confident with the process. If not, then Dignitas would inform the member that the suicide could proceed at a later date with sodium pentobarbital, after another physician consultation.

If the member was both confident with the process and capable of positioning the mask correctly, the Dignitas protocol required that the assistant explain the following:

> "[T]he assistant must explain to the member that, when the member places the mask in the prescribed and practiced manner over his or her own nose, mouth, and chin, and begins to breathe helium, he or she will, after few breaths, lose consciousness. Because breathing will continue without difficulty, the resulting oxygen deprivation will cause a breakdown of brain function. Should this breakdown persist for longer than three minutes, the consequence is virtually certain severe, permanent brain damage. Oxygen deprivation to the brain results finally in death, which will occur without the conscious realization of the member, as he or she will have long before passed out, and his or her consciousness terminated…."

The informed consent process for assisted suicide by oxygen deprivation noted that despite what had been published about the use of helium, Dignitas was inexperienced with the method and there could be 'unexpected consequences'. Members agreed that they were willing to assume these risks and that they were 'prepared to assist Dignitas in assembling its own data on the helium method', for the benefit of themselves and others (translated from German).

Variables

The main attributes for observation are time to unconsciousness, breathing patterns, movements of the extremities, eye and eyelid movements and time to reach death.

RESULTS

We present four cases of assisted suicide using helium as an alternative to sodium pentobarbital. Specific health information was not provided, but the decedents were one man and three women (aged 61, 73, 73 and 89 years). Each death took place in bed with the members resting on their backs as shown in figure 1. Data are summarised in table 3.

In each case, helium flow was initiated before the mask was put in the working position. Time is recorded with 0 s marking the moment when the member finished placing the mask in the working position.

Case 1 (male)

In accordance with the Dignitas protocol, the member exhaled deeply before placing the mask in the working position. Subsequent breathing appeared normal for approximately 35 s, and then the breathing rate accelerated. At this point (36 s), the eyelids opened, the eyeballs rolled, and the head tilted back. It is estimated that consciousness was lost approximately 36 s after the face mask was in place.

At approximately 60 s, there were purposeless movements in the arms. The left arm extended upward and reached about involuntarily. The right hand was held by an attendant, for support. The attendant appeared surprised at the arm movements. Without struggle, the attendant continued to hold the member's right hand. Gross arm movements and fine tremors lasted for approximately 1 minute. Eventually, both arms relaxed and the left arm rested with the hand under the lower back.

Approximately 3 minutes after the start of the procedure, breathing appeared to stop, except for six gasps between 3:05 and 6:30. There were two faint breaths at 7:16 and 7:55. The helium flow was shut off at 8:25. After the gas was stopped, there were four gurgled snorts at 8:38, 9:07, 9:17 and 10:15.

Case 2 (female)

After exhaling deeply and placing the mask in the working position, the member appeared to breathe normally for approximately 50 s, after which the breathing rate accelerated and the eyelids blinked rapidly. It is estimated that consciousness was lost approximately 47 s after the face mask was in place. At approximately 58 s the eyelids fixed open. At 1:05 there were tremors in the arms, arching of the back and the head tilted back. At 1:18 the neck relaxed and at 1:36 the back-arch relaxed. At 1:37 the left arm contracted at the elbow, relaxing 15 s later, and then contracting/relaxing two more times over the next 45 s. There were two more slight movements in the left arm at 6:33 and 6:46.

At 2:14 the member exhaled deeply and this was accompanied with a moaning sound that lasted for 12 s. From 2:45 through to 8:35 there were 21 short gasps, spaced apart by as few as 6 s and as long as 47 s. At 11:47 the gas flow was stopped, more than 3 minutes after the final gasp.

Case 3 (female)

This member exhaled before applying the mask to her face, but she then spoke a few words, which suggests that she may have inhaled room air before the mask was in the working position. She spent 11 s adjusting the mask in the working position and approximately 3 s after releasing her hand from the mask she uttered a few indistinct words. After the mask had been in the working position for at least 26 s, the Dignitas attendant spoke to the member. The member nodded affirmatively, indicating that she was conscious. At 52 s, the member's breathing rate began to accelerate and her eyelids fluttered and blinked. Loss of consciousness is estimated to be approximately 52 s after the face mask was in place. At 1:06 her eyelids fixed open, her head tilted back and her quickened breathing continued. At 1:21 the left hand clenched into a fist and at 2:33 the left arm slowly extended for 10 s. During this same period the member's lips vibrated with her exhaled breaths, implying relaxation of facial muscles.

At 2:23 there was a contraction of the left arm, a deep exhalation at 2:30, a contraction of the left arm at 2:50, and at 3:17 there was a big snort and extension of the left arm. At 4:03 breathing paused and then at 4:17 there were seven quick short breaths lasting to 4:33. At 4:48, 4:43 and 4:56 there were three final breaths.

Case 4 (female)

The member exhaled before placing the mask in the working position and after 30 s she appeared conscious. At 33 s she nodded 'yes' to an attendant's query whether she was breathing. Immediately afterwards the member's eyelids blinked rapidly. It is estimated that consciousness was lost 55 s after the mask was put in place. At 1:11 her eyeballs rolled and there were tremors in both hands. The tremors continued to 2:06 and then the body appeared relaxed. At 2:09 the breathing rate quickened for approximately 6 s. At 3:03 there was a slow extension and contraction of both arms, which then relaxed at the member's sides at 3:26.

At 3:58 breathing began to accelerate, pausing occasionally, and then accelerating again. From 5:36 to 10:12 there was intermittent moaning. During this same period the eyelids were open and the eyeballs were moving, but without appearance of control. Between 10:13 and 38:16, intermittent patterns of accelerated breathing, relaxed breathing and moaning continued. During this period a number of movements occurred: at 26:03 the head tilted back; at 30:41 the shoulders shrugged and left arm contracted; at 34:55 the left shoulder shrugged; at 37:06 both arms contracted for 10 s after which the member appeared quite inert.

At 38:16 the camera was turned off, to replace the video tape. The time elapsed for this is not known. The duration of the second tape is 26:57. At 0:49 of part 2 the member let out a deep gasp and the head tilted back to 0:57. At 1:31 the tongue extended slightly and withdrew. This tongue movement continued at 15–20 s intervals until 3:45, after which no further signs of life were apparent. The camera continued to run from 3:45 to 26:57, but the member appeared dead.

The recorded time from the start of the procedure to cessation of all signs of life was approximately 42 minutes. The actual time from start to finish is not known due to the change of video tape. The changes in breathing patterns, moaning and longer dying time appeared to concern and confuse the Dignitas attendants.

Table 3 Summary of findings

Case	Estimated time to loss of consciousness	Intermittent, gross extremity movements (start/finish)	Time to cessation of breathing	Terminal gasps/ breaths (time/number)
1	36 s	1 min; 2 min	3 min	3:05–6:30; 8
2	47 s	1:05; 2:37	2:45 min	2:45–8:35; 21
3	52 s	1:21; 3:17	4:03 min	4:03–4:56; 10
4	55 s	1:11; 37:16	37:16 min	Post 38 minutes*; 1

*A change of video tape prevents exact recording of time. Only one gasp is noted, but others may have occurred in the interim of tape change.

CONCLUSION

The estimated time to unconsciousness ranges from 36 to 55 s, which varies greatly from 5 to 10 s noted by Clayton and Clayton.[11] Precise determination of unconsciousness onset is not possible, but it appeared to coincide with blinking eyelids, rolling eyeballs and increased breathing rate. In general, arm movements were limited to uncoordinated contractions or extensions at the elbow. Neither attendants nor members touched the mask once it was placed in the working position. There were no attempts at self-rescue, which implies that each member was unconscious.

While the camera was focused on the dying member, the attendants could occasionally be observed, and they appeared anxious about the process. One attendant later stated that the sudden change in skin colour (cyanosis), and wide open eyelids were unexpected, because with sodium pentobarbital the loss of consciousness is slower and the eyelids tend to remain closed.

The time to death in cases 1–3 was approximately 5–10 minutes, and in case 4 it was over 40 minutes. In case 4, it is probable that sufficient oxygen was leaking into the breathing system to sustain breathing and heart function.

Although each member followed the same breathing protocol, variances in breathing patterns and total time to death can be attributed to health differences, variable rebreathing, inspiratory leaks and dilution of the inhaled mixture with room air (which would include 21% oxygen). While health information and flow rate data are unavailable, the video image reveals variances in the fit of the mask. Gaps noted between face and mask would have allowed room air to enter into the breathing environment, thereby extending the time to unconsciousness and the time to death. Even if the Dignitas attendants were trained to recognise a poor mask fit, they probably could not make adjustments without running foul of the law. This is because Swiss law requires the dying individual to perform the final act, and a third party intervention to adjust the mask would probably constitute an offence.

We conclude that much of the variability in time to unconsciousness and death can be attributed to differences in the mask fit. A hood method could reduce the problems of fit. The fit at the collar must be loose enough to serve as an exhaust port, but tight enough to ensure that the flow of gas will maintain inflation of the hood.

DISCUSSION

In these four cases, oxygen deprivation by breathing helium through a mask proved lethal. Nevertheless, we believe a mask breathing apparatus is problematical because it is very difficult to achieve and maintain a gas-tight seal between the face and the mask. Even if the initial mask fit is gas tight, subsequent involuntary movements of the head, neck and facial muscles are likely to spoil the fit. In anaesthesia, it is well known that achieving a continual airtight fit is technically difficult. Even tiny leaks may substantially allow the ingress of oxygen into the breathing environment.[12] By enhancing the video images, gaps are visible around the nose bridge and under the chin, thus room air could easily prevent an oxygen-free environment. Gaps of some degree may well have been present in all four cases.

The inspired concentration of air, and therefore oxygen, will be determined by the relative amounts of added helium and expired gas. To replace expired air completely, and thus ensure the highest possible concentration of helium, the flow rate of added gas (helium) has been determined to be a volume of at least two and a half times the individual's minute volume.[12] This would be true with either the bag and mask as used by Dignitas, or with the use of a large hood. This flow rate would require tubing of an adequate internal diameter to deliver helium from the tank to the inhalation system.

Figure 2 'Exit-bag' hood. Apparatus is similar to that described in 'Final exit' (photo RD Ogden).

'Final exit' offers detailed information about using a plastic bag hood and helium for suicide.[23] For aesthetic reasons, Dignitas chose a mask instead of a hood. A hood, however, may be easier to manage than any mask that we know. The elastic collar on a hood provides an exhaust port.

Sudden exposure to a completely oxygen-deficient environment should result in loss of consciousness within 5–10 s.[11] Given the visibly poor mask fit, and that the estimated time to unconsciousness ranged between 36 and 55 s, it is probable that the breathing environment was not completely oxygen deficient. In two case reports of sudden exposure to a helium environment inside a hood, Ogden[20] reported loss of consciousness within 10–12 s.

Assistance with suicide is not necessarily a medical procedure and these cases of oxygen deprivation show that the prescribing role of physicians and the use of drugs can be bypassed. Ziegler[2] recently noted that the Swiss model of assisted suicide has significant potential to inform the debate over the right to die, and that it 'could also help demedicalize the way that we die'. The transparency of the Swiss model and the boldness of organisations such as Dignitas provide unique opportunities to shed light upon otherwise hidden behaviours. Switzerland is probably unique in that its right-to-die organisations can account for nearly 5% of all suicides.[24] Given the nature of Swiss law and the good faith transparency and accountability of right-to-die groups in that country, the Swiss model offers unique opportunities for the observation and measurement of a phenomenon that cries out for empirical enquiry and understanding.

Acknowledgements The authors thank Cecilia Martell for assistance with translation.

Competing interests None.

Ethics approval Ethics exemption was obtained at the corresponding author's place of employment on 16 April 2008.

Provenance and peer review Not commissioned; externally peer reviewed.

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